

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

MEDLINE INDUSTRIES, INC.	)	
	)	
Plaintiff,	)	Civil Action No. 1:16-cv-3529
	)	
v.	)	The Honorable _____
	)	
	)	Magistrate Judge _____
	)	
C.R. BARD, INC.	)	<b>DEMAND FOR JURY TRIAL</b>
	)	
Defendant.	)	
_____	)	

**PLAINTIFF MEDLINE INDUSTRIES, INC.’S  
COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Medline Industries, Inc. (“Medline”), by counsel, alleges as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement. Medline brings this action to enjoin the manufacture, use, sales, offers to sell and importation by Defendant C.R. Bard, Inc. of products and methods that infringe valid and enforceable U.S. patents owned by Medline and for monetary damages for Defendant’s infringement.

**THE PARTIES**

2. Plaintiff Medline is a corporation organized under the laws of the State of Illinois, and having a principal place of business at One Medline Place, Mundelein, Illinois, 60060.

3. Founded in 1966, Medline’s roots date back to 1910 when A.L. Mills, the great-grandfather of the current leadership, sewed butcher’s aprons in Chicago. Medline has grown from a small manufacturer of aprons, surgical gowns and uniforms to a thriving \$5.8 billion

global enterprise because of its dedicated employees, entrepreneurial spirit and honest values. The company has grown into America's largest privately held national manufacturer and distributor of health care supplies and services.

4. Headquartered in Mundelein, IL since 1984, Medline manufactures and distributes more than 350,000 health care supplies and services across the continuum of care. Medline's customers include hospitals, nursing homes, surgery centers, physician offices, home care providers, home health agencies and retail outlets.

5. To serve its customers, Medline has 40 distribution centers in North America and 50 throughout the world. In addition, it has 17 manufacturing facilities worldwide.

6. In 2012, Forbes Magazine ranked Medline in the top 100 list of largest privately held companies in America. Medline employs more than 13,500 colleagues worldwide, with operations in more than 25 countries.

7. Medline leads the market in more than a dozen major medical product categories, including exam gloves, textiles, durable medical equipment, plastic patient utensils, skin care, disposable incontinence care, protective apparel, disposable drapes and gowns, and surgical procedure trays.

8. On information and belief, Defendant C.R. Bard, Inc. ("Bard") is a corporation organized under the laws of the State of New Jersey, and having a principal place of business at 730 Central Avenue, Murray Hill, New Jersey 07974.

9. On May 16, 2014 Medline filed a complaint for patent infringement in the Northern District of Illinois asserting that Bard infringes certain claims of U.S. Patent Nos. 8,448,786, 8,631,935 and 8,678,190. That litigation, entitled *Medline Industries, Inc. v. C.R.*

*Bard, Inc.*, Civil Action No.: 1:14-cv-03618-JZL-YBK, is currently pending bending before the United States District Court for the Northern District of Illinois, Eastern Division.

### **JURISDICTION AND VENUE**

10. This is a civil action for patent infringement arising under the United States patent statutes, 35 U.S.C. § 1 *et seq.*

11. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

12. Defendant Bard is subject to this Court's personal jurisdiction because it does and has done substantial business in this judicial district, including upon information and belief offering to sell in this judicial district the SureStep™ Foley Tray System, Bardex® I.C. Complete Care® Infection Control Foley Catheter Tray with Bard® Hydrogel and Bacti-Guard® Silver Alloy Coating (the "Bardex® I System"),.

13. In addition, on information and belief, Bard directly and/or through its distribution network regularly places the Bardex® I System in the stream of commerce with the knowledge and/or understanding that such products will be sold and used in Illinois and within this judicial district. Finally, Bard is subject to the general jurisdiction of this Court because it has regular and systematic contacts with this forum such that the exercise of jurisdiction over it would not offend traditional notions of fair play and substantial justice.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b) because Bard has committed acts of infringement and does business in this district.

### **BACKGROUND**

15. A urinary catheter is a thin tube placed in the bladder to drain urine. The urine drains through a tube into a collection bag. If sterility of the catheter is compromised prior to

insertion, it is possible for germs to travel along the catheter, which results in catheter-associated urinary tract infection (a.k.a. “CAUTI”).

16. At the time of the conception of the claimed inventions of the Patents-in-Suit, catheters were a common feature of hospital care, used by over four million hospital patients a year some time during their stay. Another, but seldom-discussed, reality was that the chances of a patient getting a CAUTI were generally high. In fact, the daily risk for patients acquiring a urinary infection was as high as seven percent when indwelling urethral catheters remain in their original position. Overall, such infections accounted for more than one third of all hospital-acquired infections.

17. The cumulative impact of these CAUTIs was significant, as they raised hospital costs, increased a patient’s stay and complicated their recovery. CAUTIs were a major drain on hospital resources, increasing length of stay by one to three days. At the time of the invention, such infections added approximately \$675 per patient to the costs of hospitalization. When bacteremia developed, this additional cost increased to at least \$3,800. CMS reported that in 2007 patients with CAUTIs incurred an average cost of \$44,043 per hospital stay.

18. Yet despite this, clinicians often paid little attention to the decision to insert an indwelling catheter, its optimal management or its timely removal. Supporting data also suggested that many times a urinary catheter was inserted without physician’s order, and that at times patients were not assessed appropriately for alternatives to catheterization.

### **MEDLINE’S INVENTION**

19. Medline rose to the challenge and worked to devise a solution to reduce the incidence of CAUTIs. As part of that effort, and at significant expense, Medline set out to understand the issues related to CAUTI prevention and the shortcomings of Foley catheter trays as they existed at that time.

20. Medline designed the industry's first one-layer proprietary Foley catheter tray (the "Medline Tray") to reduce the risk of CAUTI in 2009. Medline further developed methods using catheter tray assemblies in a manner that reduces the risks of CAUTI. The invention was in direct response to clinician-identified product deficits. Customers that were looking to fill those gaps responded very well to the invention and have become champions for the change.

21. Prior to the invention in the Patents-in-Suit, the conventional Foley catheter tray had two layers. The base of the tray held the drainage bag and catheter. The upper level of the tray held all of the patient preparation components. This prior generation design made it difficult to maintain a sterile field and keep the catheter aseptic while performing the procedure.

22. The inventors designed the single-layer urinary catheter tray of the claimed invention to minimize the risk of contaminating the patient or the sterile field during the catheterization procedure. By having easy access to the components, in a single layer tray (rather than a dual layer tray), the clinician can now more easily prepare and use the components within the kit/tray. Additionally, the inventors conceived step-by-step educational instructions to reinforce that the components of the tray are accessible from top to bottom, left to right in the order in which they are required in the catheterization procedure.

23. Medical facilities that purchased Medline's patent-protected ERASE CAUTI trays experienced immediate positive results. In many instances, the ERASE CAUTI trays helped bring the incidence of CAUTI to zero at the facilities.

24. Medline began selling its patent-protected ERASE CAUTI trays in 2009 and experienced success over the ensuing months and years, growing its market share.

25. Pharmaceutical & Medical Packaging News reported on Medline's ERASE CAUTI tray in March 2010, touting the tray as follows:

Medline Industries Inc.'s (Mundelein, IL) novel Foley catheter management system is a revolutionary approach to managing catheters and reducing catheter-

associated urinary tract infections (CAUTI). The shift from a two-layer tray to a one-layered tray to support the sequence of events during catheterization represents a major change for clinicians within the hospital setting. The product launched alongside a comprehensive professional awareness campaign, ERASE CAUTI, using packaging that includes a patient and family education components. Developed by Deborah Adler and Medline's urological product division and marketing division, the one-layer tray design encourages aseptic technique.

26. Pharmaceutical & Medical Packaging News interviewed physicians and nurses that had used the ERASE CAUTI tray. They reported, "[a]s educators at our facility, we were really impressed with the new Medline catheter tray design to help prevent CAUTI,' says Becky Schlabach RN, CNOR, Perioperative Educator, Goshen General Hospital (Goshen, IN). 'Medline has really done their homework on what nurses need and how to render great patient care. The tray is very intuitive, and our colleagues were pleased with and sold on the product from the first use. ... This is a great product from a great company.'"

27. Medline practices the claimed inventions. It has sold the following products that are covered by the inventions in the Patents-in-Suit:

- Latex ERASE CAUTI Foley Catheter Tray (with Drain bag and Urine Meter)
- 100% Silicone ERASE CAUTI Foley Catheter Tray (with Drain bag and Urine Meter)
- Silvertouch 100% Silicone ERASE CAUTI Foley Catheter Tray (with Drain bag and Urine Meter)
- 100% Silicone Temperature Sensing ERASE CAUTI Foley Catheter Tray (Urine Meter)
- Coude 100% Silicone ERASE CAUTI Foley Catheter Tray (drain bag)
- Coude Latex ERASE CAUTI Tray (Drain bag)
- Buddy The Brave ERASE CAUTI Foley Catheter Tray (urine meter)
- Buddy the Brave Temperature Sensing ERASE CAUTI Foley Catheter Tray (urine meter)

### **BARD REACTS**

28. On information and belief, Bard, Medline's primary competitor in the Foley catheter tray market, recognized the competitive threat posed by Medline's patent-protected ERASE CAUTI trays and began to react.

29. In 2010, Bard redesigned its Foley catheter tray and began selling a new version, which it called Advance. On information and belief, the Advance tray was designed as a response to Medline's ERASE CAUTI trays and copied certain elements of Medline's ERASE CAUTI system and program. However, the Advance tray maintained the problematic two-layer structure that had defined conventional Foley catheter trays for years.

30. In 2014, five years after Medline developed its patent-protected ERASE CAUTI trays that featured a single-layer design, Bard rolled out its SureStep system. On information and belief, the SureStep system was the first single-layer Foley catheter tray developed and/or sold by Bard. On information and belief, Bard copied Medline's single-layer design in developing the SureStep system. On information and belief, Bard's SureStep system was developed as a response to the competitive threat of Medline's patent-protected ERASE CAUTI trays.

### **THE PATENTS-IN-SUIT**

31. In recognition of the innovative features of the Medline Tray, the U.S. Patent and Trademark Office awarded multiple patents to Medline. In addition, Medline has other patents pending that protect the Medline Tray and related methods.

32. On June 10, 2014, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,746,452 ("the '452 Patent," a copy of which is attached as Exhibit A hereto), entitled "Catheter Tray, Packaging System, and Associated Methods," to

Medline in the names of inventors Jennifer E. Tomes, Deborah B. Adler, Jack E. Maze, Alberto C. Savage, Kenneth S. Chua, Earl D. Wilson and John H. Kutsch.

33. On March 15, 2016, the United States Patent and Trademark Office duly and legally issued United States Patent No. 9,283,352 (“the ‘352 Patent,” a copy of which is attached as Exhibit B hereto), entitled “Catheter Tray, Packaging System, and Associated Methods,” to Medline in the names of inventors Jennifer E. Tomes, Deborah B. Adler and Jack E. Maze.

34. Medline is the owner by assignment of the entire right, title, and interest in each of the ‘452 Patent and the ‘352 Patent (collectively, the “Medline Patents”).

### **COUNT I: INFRINGEMENT OF THE ‘452 PATENT**

35. With respect to the ‘452 Patent, Bard has been and is now directly infringing at least claim 1 of the ‘452 Patent, either literally or under the doctrine of equivalents, by making, using, importing, offering to sell, and/or selling within the United States products, including but not limited to the Bardex® I System.

#### **Notice of Infringement**

36. On information and belief, prior to the filing of the suit, Bard was aware of and analyzed the Medline Patents, including the ‘452 Patent. Bard was placed on notice of Medline’s ‘452 Patent infringement claims at least as of the filing of this Complaint.

37. Upon Bard’s gaining knowledge of the ‘452 Patent, it was apparent to Bard that the sale of the Bardex® I System infringes the ‘452 Patent.

38. On information and belief, upon Bard’s gaining knowledge of the ‘452 Patent, Bard has opted to continue its willful, deliberate, and intentional infringement of one or more claims of the ‘452 Patent at least by using, selling, importing, and/or offering to sell the Bardex® I System in reckless disregard of the claims of Medline’s ‘452 Patent.



39. Bard has acted despite an objectively high likelihood that its actions constitute an infringement of the '452 Patent. In addition, the risk of infringement was either known by Bard or so obvious to it that the risk should have been known to Bard.

### **Direct Infringement of the '452 Patent**

40. Bard has infringed the '452 Patent under Section 271 of Title 35 of the United States Code by using, selling and/or offering to sell in, and/or importing into, the United States the Bardex® I System.

41. With respect to the '452 Patent, Bard has been and is now directly infringing at least claim 1 of the '452 Patent by selling the Bardex® I System, pictured below:



42. The Bardex® I System is “a tray configured to accommodate a catheter assembly and medical devices corresponding to catheter use.” ‘452 Patent at claim 1.

43. The tray of the Bardex® I System has “a contoured surface defining at least three compartments separated by barriers and a perimeter wall.” *Id.*

44. The compartments of the tray of the Bardex® I System include “a first compartment comprising a first compartment base member having at least one inclined stair-stepped contour,” “a second compartment comprising a second base member,” and “a third compartment comprising a third base member.” *Id.*

45. The tray of the Bardex® I System includes “a first barrier separating the first compartment from the second compartment, wherein the first barrier defines a first opening between the first compartment and the second compartment, the first opening having a first opening depth.” *Id.*

46. The tray of the Bardex® I System includes “a second barrier separating the second compartment from the third compartment, wherein the second barrier defines a second opening between the second compartment and the third compartment, the second opening having a second opening depth.” *Id.*

47. Because the Bardex® I system incorporates each and every element of claim 1 of the ‘452 Patent, Bard’s sales of and/or offers to sell the Bardex® I System constitute infringement of at least claim 1 of the ‘452 Patent.

48. On information and belief, Bard’s infringement of the ‘452 Patent has been willful.

49. As a consequence of Bard’s infringement, Medline has been harmed and is entitled to recover damages adequate to compensate it for the injuries complained of herein, including lost profits, but in no event less than a reasonable royalty. Medline is further entitled to have Bard enjoined from committing additional acts of infringement, which constitute a willful violation of Medline’s rights, and which would subject Medline to irreparable harm.

50. Medline has been and will continue to be irreparably harmed by Bard’s infringement of the ‘452 Patent. Moreover, Bard’s infringement has threatened the value of the

‘452 Patent because Bard’s conduct results in Medline’s loss of its lawful patent rights to exclude others from making, using, offering to sell, selling and/or importing the patented inventions.

51. Bard’s continuing infringement has and continues to irreparably harm Medline by denying Medline the exclusive enjoyment to the inventions claimed in the Patents-in-Suit. Specifically, Bard’s infringement denies Medline the exclusive right to manufacture, sell, offer to sell, import and market Foley catheter trays covered by the Patents-in-Suit.

52. Bard’s infringement irreparably harms Medline by, among other things, eroding the price Medline may receive for its revolutionary Foley catheter trays.

53. Bard’s infringement irreparably harms Medline’s accumulated goodwill by, among other things, requiring Medline to compete against an infringing product. The competition against Bard’s infringing product requires Medline to defend the effectiveness and efficacy of its revolutionary Foley catheter tray to customers Bard is pursuing at the expense of Medline’s sales.

54. Furthermore, Bard has disparaged Medline’s revolutionary Foley catheter tray that is covered by the Patents-in-Suit to customers and potential customers of Medline.

55. Bard will derive a competitive advantage from selling, offering to sell, using and/or importing Medline’s patented technology without paying compensation for such sales, offers to sell, use and/or importation. Accordingly, unless and until Bard’s continued acts of infringement are enjoined, Medline will suffer further irreparable harm for which there is no adequate remedy at law.

## **COUNT II: INFRINGEMENT OF THE ‘352 PATENT**

56. With respect to the ‘352 Patent, Bard has been and is now directly infringing at least claim 1 of the ‘352 Patent, either literally or under the doctrine of equivalents, by making,

using, importing, offering to sell, and/or selling within the United States products, including but not limited to the Bardex® I System.

### **Notice of Infringement**

57. On information and belief, prior to the filing of the suit, Bard was aware of and analyzed the Medline Patents, including the '352 Patent. Bard has been placed on notice of Medline's '352 Patent infringement claims at least as of the filing of this Complaint.

58. Upon Bard's gaining knowledge of the '352 Patent, it was apparent to Bard that its Bardex® I System infringes the '352 Patent.

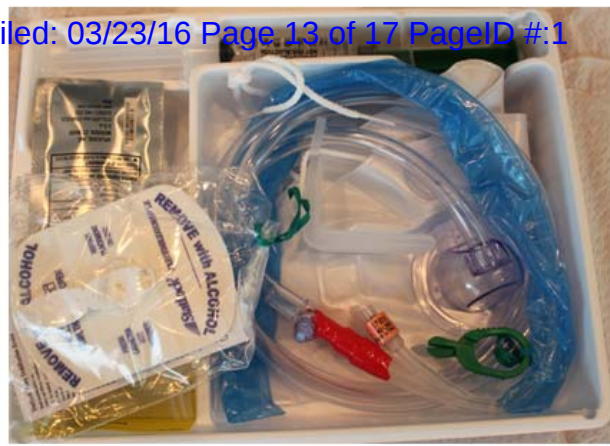
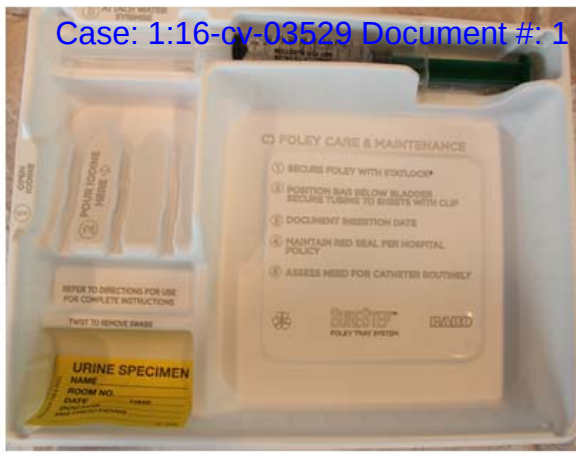
59. On information and belief, upon Bard's gaining knowledge of the '352 Patent, it has opted to continue its willful, deliberate, and intentional infringement of one or more claims of the '352 Patent at least by using, selling and/or offering to sell the Bardex® I System in reckless disregard of the claims of Medline's '352 Patent.

60. Bard has acted despite an objectively high likelihood that its actions constitute an infringement of the '352 Patent. In addition, the risk of infringement was either known by Bard or so obvious to it that the risk should have been known to Bard.

### **Direct Infringement of the '352 Patent**

61. Bard has infringed the '352 Patent under Section 271 of Title 35 of the United States Code by using, selling and/or offering to sell in, and/or importing into, the United States the Bardex® I System.

62. With respect to the '352 Patent, Bard has been and is now directly infringing at least claim 1 of the '352 Patent by selling the Bardex® I System, pictured below:



63. The Bardex® I System constitutes “a catheterization procedure system to accommodate a catheter, a fluid bag, and one or more medical devices.” ‘352 Patent at claim 1.

64. The Bardex® I System includes “a single level tray comprising a contoured surface defining at least two compartments separated by a wall.” *Id.*

65. The compartments of the Bardex® I System include “at least two compartments comprising a first compartment and a second compartment.” *Id.*

66. The Bardex® I System includes “a first syringe and a second syringe, and the catheter and the fluid bag, the catheter attached to the fluid bag.” *Id.*

67. In the Bardex® I System “the first syringe and the second syringe are disposed within the first compartment.” *Id.*

68. In the Bardex® I System “one of the first syringe or the second syringe is for use in a catheterization procedure before another of the first syringe or the second syringe and the first syringe and the second syringe are ordered within the first compartment in accordance with their use during the catheterization procedure.” *Id.*

69. In the Bardex® I System “the catheter and the fluid bag are disposed within the second compartment.” *Id.*

70. In the Bardex® I System “the first compartment defines a lubricating jelly application compartment to receive lubricating jelly from the one of the first syringe or the second syringe to lubricate the catheter when the catheter is passed from the second compartment into the first compartment.” *Id.*

71. In the Bardex® I System “the first compartment is further bounded by a first compartment base member and at least a first portion of a perimeter wall.” *Id.*

72. In the Bardex® I System “the second compartment is further bounded by a second compartment base member and at least a second portion of the perimeter wall.” *Id.*

73. In the Bardex® I System “the perimeter wall terminates at a horizontal flange.” *Id.*

74. In the Bardex® I System “the perimeter wall extends from at least a portion of the first compartment base member to the horizontal flange by a height that is greater than or equal to half of another height that the perimeter wall extends from the second compartment base member to the horizontal flange.” *Id.*

75. Because the Bardex® I system therefore has each and every element of claim 1 of the ‘352 Patent, Bard’s sales of and/or offers to sell the Bardex® I System constitute infringement of at least claim 1 of the ‘352 Patent.

76. On information and belief, Bard’s infringement of the ‘352 Patent has been willful.

77. As a consequence of Bard’s infringement, Medline has been harmed and is entitled to recover damages adequate to compensate it for the injuries complained of herein,

including lost profits, but in no event less than a reasonable royalty. Medline is further entitled to have Bard enjoined from committing additional acts of infringement, which constitute a willful violation of Medline's rights, and which would subject Medline to irreparable harm.

78. Medline has been and will continue to be irreparably harmed by Bard's infringement of the '352 Patent. Moreover, Bard's infringement has threatened the value of the '352 Patent because Bard's conduct results in Medline's loss of its lawful patent rights to exclude others from making, using, offering to sell, selling and/or importing the patented inventions.

79. Bard's continuing infringement has and continues to irreparably harm Medline by denying Medline the exclusive enjoyment to the inventions claimed in the Patents-in-Suit. Specifically, Bard's infringement denies Medline the exclusive right to manufacture, sell, offer to sell, import and market Foley catheter trays covered by the Patents-in-Suit.

80. Bard's infringement irreparably harms Medline by, among other things, eroding the price Medline may receive for its revolutionary Foley catheter trays.

81. Bard's infringement irreparably harms Medline's accumulated goodwill by, among other things, requiring Medline to compete against an infringing product. The competition against Bard's infringing product requires Medline to defend the effectiveness and efficacy of its revolutionary Foley catheter tray to customers Bard is pursuing at the expense of Medline's sales.

82. Furthermore, Bard has disparaged Medline's revolutionary Foley catheter tray that is covered by the Patents-in-Suit to customers and potential customers of Medline.

83. Bard will derive a competitive advantage from selling, offering to sell, using and/or importing Medline's patented technology without paying compensation for such sales, offers to sell, use and/or importation. Accordingly, unless and until Bard's continued acts of

infringement are enjoined, Medline will suffer further irreparable harm for which there is no adequate remedy at law.

**REQUEST FOR RELIEF**

WHEREFORE, Medline respectfully requests the following relief:

- A. A judgment holding Bard liable for infringement of the '452 Patent and the '352 Patent;
- B. A permanent injunction against Bard, its officers, agents, servants, employees, attorneys, parent and subsidiary corporations, assigns and successors in interest, and those persons in active concert or participation with them, enjoining them from continued acts of infringement of the '452 Patent and the '352 Patent;
- C. Damages to compensate Medline for injuries resulting from Bard's infringement of the '452 Patent and the '352 Patent, together with pre-judgment and post-judgment interest;
- D. Pursuant to 35 U.S.C. § 284, a judgment trebling damages awarded to Medline due to Bard's willful infringement of the '452 Patent and the '352 Patent;
- E. A judgment holding this Action an exceptional case, and an award to Medline for its attorneys' fees and costs pursuant to 35 U.S.C. § 285; and
- F. Such other relief as the Court deems just and equitable.



Dated: March 23, 2016

Respectfully submitted,

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